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| APPLICATION NO.                        | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/737,245                             | 12/15/2003  | Palani Balu          | AFY-2068-CT         | 5841             |
| 35938                                  | 7590        | 01/11/2007           | EXAMINER            |                  |
| BIOTECHNOLOGY LAW GROUP                |             |                      | KAM, CHIH MIN       |                  |
| C/O PORTFOLIOIP                        |             |                      | ART UNIT            | PAPER NUMBER     |
| PO BOX 52050                           |             |                      | 1656                |                  |
| MINNEAPOLIS, MN 55402                  |             |                      |                     |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE   |                      | DELIVERY MODE       |                  |
| 3 MONTHS                               | 01/11/2007  |                      | PAPER               |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                          |                  |
|------------------------------|--------------------------|------------------|
| <b>Office Action Summary</b> | Application No.          | Applicant(s)     |
|                              | 10/737,245               | BALU, PALANI     |
|                              | Examiner<br>Chih-Min Kam | Art Unit<br>1656 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 10-18 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 10-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 December 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. In the preliminary amendment filed December 15, 2003, claims 1-9 have been cancelled, and new claims 10-18 have been added. Therefore, claims 10-18 are examined.  
The status of claims should be indicated, e.g., claims 10-18 (new).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 11-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 11-17 are indefinite because of the use of the term "to minimize...." or "a type". The terms cited render the claim indefinite, it is not clear how much of the reaction product for the intermolecular disulfide bond formed refers to the term "to minimize....", and what type of oxidizing reagent the term "a type" refers to. Claims 12-17 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.
4. Claim 15 is indefinite because the claim has the same scope as claim 14.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10-11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Wrighton *et al.* (U. S. Patent 5,773,569).

Wrighton *et al.* teach a dimeric peptide analog of GGTYSCHFGPLTWVCKPQGG (claim 18) containing two disulfide bonds was prepared by providing a linking moiety (Knorr linker) with a first and second functional group capable of serving as initiation sites for peptide synthesis and a third functional group attachable to a solid support; binding the linking moiety to the solid support; synthesizing the first peptide and then the second peptide wherein each peptide contains two cysteines (claim 10, step (a)); cleaving the synthesized peptide from the solid support and purifying the peptide; and cyclizing the peptide via forming the first disulfide bond, and subsequently forming the second disulfide bond to yield the bicyclic dimer (column 18, lines 25-40; Fig. 12; claim 10, step (b), 11).

#### ***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 10-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent 6,703,480. Although the

conflicting claims are not identical, they are not patentably distinct from each other because claims 10-18 disclose a method for synthesizing a peptide dimer, comprising: (a) providing first and second peptide chains linked to a linking moiety  $L_k$ , the chains are capable of disulfide bond formation upon oxidation; and (b) oxidizing the peptide chains in a manner effective to preferentially promote formation of disulfide bonds in the same peptide chain relative to formation of disulfide bonds in different peptide chains, and wherein at least 50% of said peptide dimer comprises a peptide chain having an intrapeptide disulfide bond. This is an obvious variation in view of claims 1-8 in the patent which discloses a method of synthesizing a peptide dimer, comprising: (a) providing a linking moiety  $L_k$  having first and second functional groups serving as initiation sites for peptide synthesis, and a third functional group attachable to a solid support; (b) binding the linking moiety  $L_k$  to a solid support through the third functional group; (c) synthesizing a first peptide chain at the first functional group and a second peptide chain at the second functional group, wherein each of said first and second peptide chains contain two cysteine residues positioned to allow intramolecular cyclization through a disulfide bond, and wherein synthesizing the first peptide chain and synthesizing the second peptide chain occur simultaneously; (d) cleaving said peptide chains from said solid support; and (e) oxidizing said peptide chains with an oxidizing composition effective to promote formation of disulfide bonds between cysteine residues in the same peptide chain while minimizing formation of disulfide bonds between cysteine residues in different peptide chains, wherein about 50% or greater of said peptide dimer comprises a peptide chain having an intrapeptide disulfide bond. Both the claims of instant application and the claims of the patent are directed to a method of synthesizing a peptide dimer, comprising providing first and second

peptide chains linked to a linking moiety LK, the chains are capable of disulfide bond formation upon oxidation; and oxidizing the peptide chains in a manner effective to promote formation of disulfide bonds in the same peptide chain. Thus, claims 10-18 in present application and claims 1-8 in the patent are obvious variations of a method of synthesizing a peptide dimer, comprising providing first and second peptide chains linked to a linking moiety LK; and oxidizing the peptide chains in a manner effective to promote formation of disulfide bonds in the same peptide chain.

***Conclusion***

7. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

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January 5, 2007